

08-09-04

IFW

PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Application Number

10/773,706

Filing Date

12/11/2003

First Named Inventor

James E. Hagstrom, et al.

Group Art Unit

Examiner Name

Total Number of Pages in This Submission **144**

Attorney Docket Number

48.01

ENCLOSURES (check all that apply)

- ☐ Fee Transmittal Form
☐ Fee Attached
☐ Amendment / Reply
☐ After Final
☐ Affidavits/declaration(s)
☐ Extension of Time Request
☐ Express Abandonment Request
☒ Information Disclosure Statement
☐ Certified Copy of Priority Document(s)
☐ Response to Missing Parts/
Incomplete Application
☐ Response to Missing Parts
under 37 CFR 1.52 or 1.53

- ☐ Assignment Papers
(for an Application)
☐ Drawing(s)
☐ Licensing-related Papers
☐ Petition
☐ Petition to Convert to a
Provisional Application
☐ Power of Attorney, Revocation
Change of Correspondence
Address
☐ Terminal Disclaimer
☐ Request for Refund
☐ CD, Number of CD(s) _____

- ☐ After Allowance Communication
to Group
☐ Appeal Communication to Board
of Appeals and Interferences
☐ Appeal Communication to Group
(Appeal Notice, Brief, Reply Brief)
☐ Proprietary Information
☐ Status Letter
☐ Other Enclosure(s) (please
identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENTFirm
or
Individual name

Mirus Corporation

Signature

Date

08/02/2004

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date:

08/07/2004

Typed or printed name

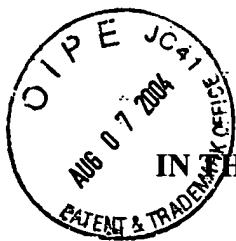
Mark K. Johnson

Signature

Date

08/07/2004

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: James E. Hagstrom,)
Jon A. Wolff, Vladimir G. Budker,)
Julia Hegge, Hans Herweijer)
Serial No.: 10/773,706)
Filed: 12/11/2003)
Group Art Unit: not assigned)

For: A Process Of Delivering A Virally Encapsulated Polynucleotide Or Viral Vector To A Parenchymal Cell Via The Vascular System

INFORMATIONAL STATEMENT

Commissioner of Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449. This information statement supplements the previously filed information statement.

US patent

6,627,616 issued: 09/20/2003 Mirus Corporation filed: 11/23/1999

REFERENCES CITED

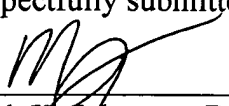
- Acsadi Get al. "Direct gene transfer and expression into rat heart in vivo" The New Biologist; 1991 Vol. 3 no. 1 pp. 71-81
Budker V et al. "The efficient expression of intravascularly delivered DNA in rat muscle," Gene Therapy; 1998 Vol. 5 no. 2 pp. 272-276
Chapman G et al. "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," Circ. Res; 1992 Vol. 71 pp. 27-33
Chowdhury JR et al. "Long-term improvement of hypercholesterolemia after ex vivo gene therapy in LDLR-deficient rabbits," Science; 1991 Vol. 254 pp. 1802-1805
Ferry N et al. "Retroviral-mediated gene transfer into hepatocytes in vivo," Proc Natl Acad Sci USA; 1991 Vol. 88 pp. 8377-8381
Greelish JP et al. "Stable restoration of the sarcoglycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector." Nature; 1999 Vol. 5 no. 4 pp. 439-443

- Grossman M et al. "Successful ex vivo gene therapy directed to liver in a patient with familial hypercholesterolaemia," *Nature Genetics*; 1994 Vol. 6 pp. 335-341
- Hengge UR et al. "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," *Nature Genetics*; 1995 Vol. 10 pp. 161-166
- Hickman MA et al. "Gene expression following direct injection of DNA into liver," *Human Gene Therapy*; 1994 Vol. 5 pp. 1477-1483
- Jaffe HA et al. "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," *Nat. Genet*; 1992 Vol. 1 pp. 372-378
- Kaleko M et al. "Persistent gene expression after retroviral gene transfer into liver cells in vivo," *Hum Gene Ther*; 1991 Vol. 2 pp. 27-32
- Kaneda Y et al. "Introduction and expression of the human insulin gene in adult rat liver," *J Biol Chem*; 1989 Vol. 264 pp. 12126-12129
- Kaneda Y et al. "Increased expression of DNA cointroduced with nuclear protein in adult rat liver," *Science*; 1989 Vol. 243 pp. 375-378
- Kay MA et al. "Hepatic gene therapy: persistent expression of human alpha 1-antitrypsin in mice after direct gene delivery in vivo," *Hum Gene Ther*; 1992 Vol. 3 pp. 641-647
- Ledley FD et al. "Retroviral gene transfer into primary hepatocytes: implications for genetic therapy of liver-specific functions," *PNAS*; 1987 Vol. 84 pp. 5335-5339
- Li Q et al. "Assessment of recombinant adenoviral vectors for hepatic gene therapy," *Hum. Gene Ther*; 1993 Vol. 4 pp. 403-490
- Liu F et al. "Hydrodynamics-based transfection in animals by systemic administration of plasmid DNA," *Gene Ther*; 1999 Vol. 6 pp. 1258-1266
- Malone RW et al. "Dexamethasone enhancement of gene expression after direct hepatic DNA injection," *J Biol Chem*; 1994 Vol. 269 pp. 29903-29907
- Meyer KB et al. "Intratracheal gene delivery to the mouse airway: characterization of plasmid DNA expression and pharmacokinetics," *Gene Ther*; 1995 Vol. 2 pp. 450-460
- Milas M et al. "Isolated limb perfusion in the sarcoma-bearing rat: a novel preclinical gene delivery system," *Clin Cancer Res*; 1997 Vol. 3 no. 12 Pt. 1, pp. 2197-203
- Riessen et al. "Arterial gene transfer using pure DNA applied directly to a hydrogel-coated angioplasty balloon," *Human Gene Ther*; 1993 Vol. 4 pp. 749-758
- Sikes M et al. "In vivo gene transfer into rabbit thyroid follicular cells by direct DNA injection," *Hum. Gene Ther*; 1994 Vol. 5 p. 837-844
- Soriano P et al. "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," *PNAS*; 1983 Vol. 80 pp. 7128-7131
- Stratford-Perricaudet LD et al. "Evaluation of the transfer and expression in mice of an enzyme-encoding gene using a human adenovirus vector," *Hum. Gene Ther*; 1990 Vol. 1 pp. 241-256
- Vile RG et al. "In vitro and in vivo targeting of gene expression to melanoma cells," *Cancer Res*; 1993 Vol. 53 pp. 962-967
- Wolff JA et al. "Expression of retrovirally transduced genes in primary cultures of adult rat hepatocytes," *Proc Natl Acad Sci USA*; 1987 Vol. 84 pp. 3344-3348
- Wolff JA et al. "Direct gene transfer into mouse muscle in vivo," *Science*; 1990 Vol. 247 pp. 1465-1468
- Yang Y et al. "Immune responses to viral antigens versus transgene product in the elimination of recombinant adenovirus-infected hepatocytes in vivo," *Gene Therapy*; 1996 Vol. 3 no. 2 pp. 137-144

Zhang G et al. "High Levels of Foreign Gene Expression in Hepatocytes after Tail Vein Injections of Naked Plasmid DNA," Human Gene Therapy; 1999 Vol. 10 pp. 1735-1737
Zhang et al. "Efficient expression of naked dna delivered intraarterially to limb muscles of nonhuman primates," Human Gene Therapy 2001 Vol. 12 no. 4 pp. 427-438

Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

Respectfully submitted,



Mark K. Johnson Reg. No. 35,909
P.O. Box 510644
New Berlin, WI 53151-0644
(414) 821-5690

I hereby certify that this correspondence is being sent by
United States Postal Service mail to: Commissioner for
Patents, PO Box 1450, Alexandria, VA 22313-1450 on:
~~November 6, 2003~~ 8-2-01



Kirk Ekena

INFORMATION DISCLOSURE STATEMENT BY APPLICANT FORM PTO-1449	Attorney Docket No.: Mirus.048.01	Serial No.: 10/773,706
	Applicant: James E. Hagstrom, Jon A. Wolff, Vladimir G. Budker, Julia Hegge, Hans Herweijer	Group:
		Examiner:

U.S. PATENT DOCUMENTS

Exmnr Intl	Seq	Patent Number	Issue Date	Patentee	Class	Sub Class	Filing Date
		6,627,616	09/20/2003	Mirus Corporation	514	44	11/23/1999

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		Document Number	Publication Date	Country or Patent Office	Class	Sub Class	Transl.	
							yes	no

OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

		Acsadi Get al. "Direct gene transfer and expression into rat heart in vivo" The New Biologist; 1991 Vol. 3 no. 1 pp. 71-81
		Budker V et al. "The efficient expression of intravascularly delivered DNA in rat muscle," Gene Therapy; 1998 Vol. 5 no. 2 pp. 272-276
		Chapman G et al. "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," Circ. Res; 1992 Vol. 71 pp. 27-33
		Chowdhury JR et al. "Long-term improvement of hypercholesterolemia after ex vivo gene therapy in LDLR-deficient rabbits," Science; 1991 Vol. 254 pp. 1802-1805
		Ferry N et al. "Retroviral-mediated gene transfer into hepatocytes in vivo," Proc Natl Acad Sci USA; 1991 Vol. 88 pp. 8377-8381
		Greelish JP et al. "Stable restoration of the sarcoglycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector." Nature; 1999 Vol. 5 no. 4 pp. 439-443
		Grossman M et al. "Successful ex vivo gene therapy directed to liver in a patient with familial hypercholesterolaemia," Nature Genetics; 1994 Vol. 6 pp. 335-341
		Hengge UR et al. "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," Nature Genetics; 1995 Vol. 10 pp. 161-166
		Hickman MA et al. "Gene expression following direct injection of DNA into liver," Human Gene Therapy; 1994 Vol. 5 pp. 1477-1483
		Jaffe HA et al. "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," Nat. Genet; 1992 Vol. 1 pp. 372-378
		Kaleko M et al. "Persistent gene expression after retroviral gene transfer into liver cells in vivo," Hum Gene Ther; 1991 Vol. 2 pp. 27-32
		Kaneda Y et al. "Introduction and expression of the human insulin gene in adult rat liver," J Biol Chem; 1989 Vol. 264 pp. 12126-12129
		Kaneda Y et al. "Increased expression of DNA cointroduced with nuclear protein in adult rat liver," Science; 1989 Vol. 243 pp. 375-378
		Kay MA et al. "Hepatic gene therapy: persistent expression of human alpha 1-antitrypsin in mice after direct gene delivery in vivo," Hum Gene Ther; 1992 Vol. 3 pp. 641-647

		Ledley FD et al. "Retroviral gene transfer into primary hepatocytes: implications for genetic therapy of liver-specific functions," PNAS; 1987 Vol. 84 pp. 5335-5339
		Li Q et al. "Assessment of recombinant adenoviral vectors for hepatic gene therapy," Hum. Gene Ther; 1993 Vol. 4 pp. 403-490
		Liu F et al. "Hydrodynamics-based transfection in animals by systemic administration of plasmid DNA," Gene Ther; 1999 Vol. 6 pp. 1258-1266
		Malone RW et al. "Dexamethasone enhancement of gene expression after direct hepatic DNA injection," J Biol Chem; 1994 Vol. 269 pp. 29903-29907
		Meyer KB et al. "Intratracheal gene delivery to the mouse airway: characterization of plasmid DNA expression and pharmacokinetics," Gene Ther; 1995 Vol. 2 pp. 450-460
		Milas M et al. "Isolated limb perfusion in the sarcoma-bearing rat: a novel preclinical gene delivery system," Clin Cancer Res; 1997 Vol. 3 no. 12 Pt. 1, pp. 2197-203
		Riessen et al. "Arterial gene transfer using pure DNA applied directly to a hydrogel-coated angioplasty balloon," Human Gene Ther; 1993 Vol. 4 pp. 749-758
		Sikes M et al. "In vivo gene transfer into rabbit thyroid follicular cells by direct DNA injection," Hum. Gene Ther; 1994 Vol. 5 p. 837-844
		Soriano P et al. "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," PNAS; 1983 Vol. 80 pp. 7128-7131
		Stratford-Perricaudet LD et al. "Evaluation of the transfer and expression in mice of an enzyme-encoding gene using a human adenovirus vector," Hum. Gene Ther; 1990 Vol. 1 pp. 241-256
		Vile RG et al. "In vitro and in vivo targeting of gene expression to melanoma cells," Cancer Res; 1993 Vol. 53 pp. 962-967
		Wolff JA et al. "Expression of retrovirally transduced genes in primary cultures of adult rat hepatocytes," Proc Natl Acad Sci USA; 1987 Vol. 84 pp. 3344-3348
		Wolff JA et al. "Direct gene transfer into mouse muscle in vivo," Science; 1990 Vol. 247 pp. 1465-1468
		Yang Y et al. "Immune responses to viral antigens versus transgene product in the elimination of recombinant adenovirus-infected hepatocytes in vivo," Gene Therapy; 1996 Vol. 3 no. 2 pp. 137-144
		Zhang G et al. "High Levels of Foreign Gene Expression in Hepatocytes after Tail Vein Injections of Naked Plasmid DNA," Human Gene Therapy; 1999 Vol. 10 pp. 1735-1737
		Zhang et al. "Efficient expression of naked dna delivered intraarterially to limb muscles of nonhuman primates," Human Gene Therapy 2001 Vol. 12 no. 4 pp. 427-438

Examiner:	Date Considered:
-----------	------------------